K051947

AUG 2 2 2005

Attachment VI: Summary of Safety and Effectiveness Information [510(k) Summary]

SUBMITTER:	Radionics, a division of Tyco Healthcare LP 22 Terry Ave. Burlington, MA 01803 Tel.: (781) 272-1233 Fax: (781) 238-0645 Contact: Kevin J. O'Connell Regulatory Affairs Manager
PROPRIETARY NAME:	Radionics CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip
COMMON OR USUAL NAME:	Ultrasonic Aspirator
CLASSIFICATION CODE:	Unclassified
PREDICATE DEVICES:	CUSA Excel Ultrasonic Surgical aspirator System, K981262. Cavitron Ultasonic Surgical Aspirator CUSA System Model NS-100, K801623. Synergetics Sonotome Ultrasonic Aspirator Tips, K020220.
INTENDED USE:	The CUSA Excel Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable, including Neurosurgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery and Thoracoscopic Surgery.
DESCRIPTION:	The CUSA Excel Ultrasonic Surgical Aspirator System (CUSA) is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissue while preserving vessels, ducts and other delicate structures. The CUSA Excel System consists of a console which provides control and power functions, a surgical handpiece which provides ultrasonic mechanical energy, a titanium handpiece tip and flexible irrigation flue, and a suction/irrigation system (manifold tubing and cooling water canister). A tip has been added to the CUSA Excel system to enable it to abrade bone. Testing was completed to demonstrate that the tip will abrade bone. The tip is manufactured from the same materials as in the other CUSA Excel tips.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 2 2005

Mr. Kevin J. O'Connell
Regulatory Affairs Manager
Radionics, a division of Tyco Healthcare LP
22 Terry Avenue
Burlington, Massachusetts 01803

Re: K051947
Trade/Device Name: Radionics CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: LFL
Dated: July 15, 2005
Received: July 18, 2005

Dear Mr. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051947

Indications for Use

510(k) Number (if known): K051947

Device Name: Radionics CUSA Excel Ultrasonic Surgical Aspirator System with Bone Tip

Indications For use: The CUSA Excel Ultrasonic Surgical Aspirator System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft and hard (e.g.: bone) tissue is desirable, including Neurosurgery, Plastic and Reconstructive Surgery, General Surgery, Orthopedic Surgery, Gynecological Surgery, Thoracic Surgery, Laparoscopic Surgery and Thoracoscopic Surgery.

PRESCRIPTION USE __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucheit for M&M

(Division Sign-Off)
Division of General, Rest... and Neurological Devices

510(k) Number K051947